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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/569,486

02/24/2006

Weiqi Wang

2185-0789PUS1

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EXAMINER

BIANCHI, KRISTIN A

ART UNIT

PAPER NUMBER

1626

NOTIFICATION DATE

DELIVERY MODE

09/16/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No. 10/569,486	Applicant(s) WANG ET AL.	
	Examiner KRISTIN BIANCHI	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 5-9 is/are rejected.
- 7) ☒ Claim(s) 4 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☒ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>02/24/2006 and 10/13/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-9 are currently pending in the instant application. Claims 1-3 and 5-9 are rejected. Claim 4 is objected.

Information Disclosure Statement

The information disclosure statement filed February 24, 2006 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. Foreign document JP-11-217356-A listed on the information disclosure statement has not been received. This document has been crossed out in the signed copy of the 1449 form submitted herewith; the rest of the documents on the list have been considered. The information disclosure statement filed October 13, 2006 has met all the conditions of 37 CFR 1.97 and 1.98, has been considered and a signed copy of the 1449 form has been submitted herewith.

Priority

Applicant is claiming the benefit of foreign priority document 2003-209042 filed on August 27, 2003. However, an English copy of this document has not been received in this application. Also, acknowledgment is made of applicant's claim for the benefit of foreign priority document 2003-384566 filed on November 14, 2003. It is noted, however, that applicant has not filed a certified copy of 2003-384566 as required by 35 U.S.C. 119(b).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

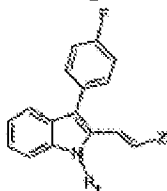
The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-3 and 5-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 01/92223 in view of WO 03/024958 and Berkaoui et al.

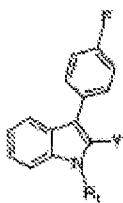
Determination of the scope and contents of the prior art.

WO 01/92223 discloses (page 5) the production of compounds which are of the following formula (6):



wherein Z is the radical –COOR₄, –COR₅, or –CN wherein R₄ is hydrogen or a hydrocarbon radical and R₅ is a hydrocarbon radical or unsubstituted or substituted amino through the reaction of compounds of formula (5) or

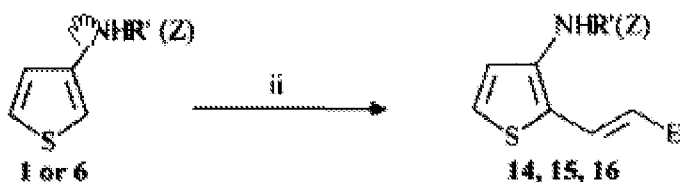
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with a compound that introduces the radical of formula $-\text{CH}=\text{CH}-\text{Z}$ wherein Z is defined as above. Compounds of formula (6) are used as intermediates in the synthesis of compounds (i.e. of formula (1)) which are known as pharmaceutical active ingredients (page 1).

WO 03/024958 discloses (page 13, Example 1) the preparation of 1,1,1-Trifluoro-4-(4-methylphenyl)-3-buten-2-one by adding zinc chloride to a solution of toluene and 4-ethoxy-1,1,1-trifluoro-3-buten-2-one in dichloromethane.

Berkaoui et al. discloses (page 9057) the following reaction:



which involves the reaction of $\text{ECH}_2\text{CH}(\text{OMe})_2$ wherein E is COMe, COOMe or CN with 1 wherein R' or Z can be H (page 9056) in CH_2Cl_2 and in the presence of HCl.

Ascertaining the differences between the prior art and the claims at issue.

WO 01/92223 discloses the production of compounds with the exact same formula as in the instant claims, however, WO 01/92223 does not carry out the same reaction that is disclosed in the instant claims for the production of these compounds.

WO 03/024958 discloses the preparation of 1,1,1-Trifluoro-4-(4-methylphenyl)-3-buten-2-one which is the same reaction as disclosed in the instant claims (i.e. the Ar-H compound is reacted with a $\text{Z}-\text{C}=\text{C}-\text{Y}$ compound in the presence of an acid), however, the reaction disclosed in WO 03/024958 is carried out in a different solvent than in the instant claims.

Berkaoui et al. discloses the preparation of compounds 14, 15 or 16 which is the same reaction as disclosed in the instant claims (i.e. the Ar-H compound is reacted with a



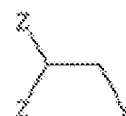
compound in the presence of an acid), however, the reaction is carried out in a different solvent than in the instant claims.

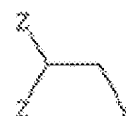
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Resolving the level of ordinary skill in the pertinent art – Prima Facie Case of Obviousness.

It would have been obvious to one of ordinary skill in the art at the time of the invention to make compounds of the formula (6) disclosed in WO 01/92223 by way of the reaction disclosed in the instant claims given the reactions disclosed in WO 03/024958 and Berkaoui et al. since an indolyl group and a phenyl group are both aromatic. It is common practice for a person skilled in the art to carry out a synthesis in different solvent conditions in an attempt to optimize a synthesis. Further, the courts have stated that changes in process conditions of an old process does not impart patentability in the absence of unexpected results. In re Boesch, 205 USPQ 215 (1980). In re Aller et al. (CCPA 1955) 220 F2d 454. In re Dunn, 146 USPQ 479 (i.e. use of a conventional solvent in an otherwise known process is not a patentable modification).

One of ordinary skill would have reasonable expectation of success in practicing the instantly claimed process given the prior art references. One would be motivated to carry out the instant process in an attempt to find optimal conditions for carrying out a



known process (i.e. reacting an Ar-H with a Z-C=C-Y or  compound in the presence of an acid is known in the art as can be seen from the prior art references) which results in compounds which are known to be pharmaceutical active ingredients. Therefore, the instant claims are *prima facie* obvious.

Claim Objections

Claim 4 is objected for depending on a rejected base claim.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KRISTIN BIANCHI whose telephone number is (571)270-5232. The examiner can normally be reached on Mon-Fri 7am-3:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kamal A Saeed, Ph.D./
Primary Examiner, Art Unit 1626

Kristin Bianchi
Examiner
Art Unit 1626
